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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,085	03/04/2002	George N. Lambrou	OP/4-31902A/USN	4270

1095 7590 07/27/2004

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER

KWON, BRIAN YONG S

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/090,085

**Applicant(s)**

LAMBROU ET AL.

**Examiner**

Brian S Kwon

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-6, 9-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-2, 5-6 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed (WO 98/41208).

The claims read on a method for opening potassium channels in the cell membranes of a mammal in need of such treatment comprising administering to the mammal an effective amount of a compound of the formula (in claim 1 and claim 2), namely unoprostone isopropyl, wherein said condition or disease state is hypertension, pulmonary hypertension, asthma, interstitial cystitis, urinary incontinence and other urogenital disorders, ischemic bowel disease, gastrointestinal motility disorders, arrhythmias, peripheral vascular disease, congestive heart failure, dysmenorrhea, angina or alopecia.

Reed teaches the ophthalmic administration of isopropyl unoprostone for the treatment of ocular hypertension, wherein said isopropyl unoprostone is administered within the dosage range of about 0.001 to about 0.30 weight percent (Examples 1-3). Examples 1-3, especially Table I, shows the efficacy of about 0.12% to about 0.18% isopropyl unoprostone in lowering intraocular pressure wherein about 30 microliters of the formulation were instilled into the eye of a rabbit.

Although Reed is silent about the activity of isopropyl unoprostone in opening potassium channels in the cell membranes of a mammal, such property or characteristics deems to be inherent to the prior art method of treating ocular hypertension. Especially in light of the instant disclosure (page 9, lines 7-12), the prior art administered dosage of isopropyl unoprostone in treating ocular hypertension lies well within the instantly claimed dosage range. Therefore, the prior art method directing the administration of isopropyl unoprostone inherently possessing a therapeutic effect for the same ultimate purpose as disclosed by Applicants anticipates Applicants's claims even absent explicit recitations of the mechanism of action.

### *Response to Arguments*

2. Applicant's arguments filed 3/10/2004 have been fully considered but they are not persuasive.

Applicant asserts that ocular hypertension is a completely different condition from hypertension, pulmonary hypertension and the other conditions or disease states recited in claims 9 and 10. Applicant alleges that since Reed fails to teach treating hypertension, pulmonary hypertension or any other of the conditions or diseases states recited in claims 9 and 10 with isopropyl unoprostone, the activity of isopropyl unoprostone in opening potassium channels in the cell membranes of mammals cannot be deemed an inherent property of treating these specific conditions or disease states.

This argument is not persuasive at all. Unlike applicant's allegation, the instant scope of "hypertension" encompasses ocular hypertension. The instantly claimed "hypertension" does not exclude that the claimed high blood pressure condition

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(hypertension) is only limited to pulmonary origin or any other specific location. Rather, the term covers high blood pressure condition in any location, including ocular blood vessels. Therefore, the reference anticipates the claimed invention. ) The prior art method directing the administration of isopropyl unoprostone inherently possessing a therapeutic effect for the same ultimate purpose as disclosed by Applicants anticipates Applicant's claims even absent explicit recitations of the mechanism of action.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

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Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon  
Patent Examiner  
AU 1614

**ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1600**

A handwritten signature in cursive script, appearing to read "Zohreh Fay", written in black ink.